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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,443	12/16/2003	Howard A. Fields	14114.0342U3	8740

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/738,443	FIELDS ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/15//2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-53* is/are pending in the application.

4a) Of the above claim(s) *48-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to communication received 5/15/2006. The status of the claims is as follows: claims 1-43 are cancelled, claims 43-47 are under examination and claims 48-53 are pending.

Applicant's election with traverse of a method of detecting the presence of antibodies against Hepatitis A virus in the reply filed on 5/15/2006 is acknowledged. The traversal is on the ground(s) that search of Group I and II together would not create a serious burden. This is not found persuasive because not only are the inventions of either group distinct from each other, they would also require a search within different arts. A method aimed towards enhancing immunoreactivity of a synthetic peptide to an IgM is not comparable to a method of diagnosis of Hepatitis A virus.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections

35 U.S.C. 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Based on the recitation "at least *about* nine amino acid residues in length to ***about*** 35 amino acids in length", it is unclear what the length of the peptide is (for example, about 35 may encompass 31, 32,

33, 34, 35, 36, 37 etc.). Because with this recitation one cannot determine the metes and bounds of the patent protection desired, claims 44-47 are rejected. Clarification is required.

35 U.S.C. 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims read on any and all synthetic peptides that are immunoreactive with antibodies directed against HAV or, more specifically, HAV in the acute phase of infection.

The following quotation from section 2163 of the MPEP is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately

> described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed or through disclosure of a functional characteristic of the claimed genus coupled with a known or disclosed non-functional characteristic (structure) that correlates to the function.

In the instant case, the applicant fails to demonstrate the distinguishing characteristics necessary for the peptide to bind to HAV antibodies. For example, the specification fails to disclose structural epitopes of antibodies against Hepatitis A virus in which the peptides would bind. The specification does not disclose epitopes that specifically correlates to the detection of the acute phase of Hepatitis A infection (claims 46 and 47) that would distinguish them from other phases. It is further noted that HAV comprises many proteins and thus, encompassing many epitopes yet the claims are not drawn to any particular peptide. Because the Applicant has not provided a representative number of examples of identifying characteristics by which those in the art could recognize the claimed genus or a correlation of structure to function, the claims are rejected for lack of written description.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 44-45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2 7 and 9 of U.S. Patent No. 6,838,237. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species prior art anticipates a genus of the current application.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a method for detecting the presence of antibodies against Hepatitis A virus with synthetic peptides that are 9-35 a.a. in length and

immunoreactive with antibodies directed against Hepatitis A virus. Further, the peptides have one or more glutamines at its C-terminal end. This method comprises the following steps: contact of peptide to said antibody and detection of the binding of peptide to antibody. The antibodies are in a biological sample, including serum or blood (page 35, lines 10-11) from the subject.

Determining the Scope and Content of the Prior Art

Claims 1, 2, 7 and 9 of U. S. Patent No. US 6,838,237 are drawn to a method or products of detecting the presence of antibodies against HAV in mammalian serum. The method comprises contacting one or more HAV peptides with antibodies from mammalian serum and detecting the formation of complexes between the peptide and the antibodies. The peptide is selected from SEQ ID NOS: 1-72. Claims 7 and 9 are drawn to peptides (SEQ ID NOS: 46 and 48) within the 9-35 a.a. range and each have a glutamine residue at their C-terminal ends.

Ascertaining the Differences Between the Prior Art and the Instant Application

Claim 44 of the current application is drawn to peptides defined by structural limitations, such as length and residues at the C-terminal end. The peptides are defined as having "at least about nine amino acid residues in length to about 35 amino acid residues in length with one or more molecules of the amino acid glutamine at the carboxyl terminal". In contrast, the prior art discloses specific peptides from SEQ ID NO: 1-72.

Finding Prima Facie Obviousness

The instant application is obvious in view of the prior art to one of ordinary skill. The claims of both describe method steps (eg contact of peptide to antibody and detection) and goals (detection of antibodies against Hepatitis A) that are nearly identical. Further, the prior art discloses peptides that are between 9-35 a.a. in length and have a Gln at its C-terminal end, e.g. SEQ ID NOS: 46 and 48. Of note, claim 2 of the prior art is drawn to an immunogenic peptide that "*has the amino acid sequence of SEQ ID NO:47* and conservative variations thereof."

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

CONCLUSION

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see htt://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michelle Horning
Patent Examiner

JEFFREY S. PARKIN, PH.D.
SUPERVISORY EXAMINER